

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

CUSTOMER NO.

42-F-0008

1726

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

CVB-VS-APHIS-USDA

1800 Dayton Avenue

Ames, IA 50010 (515) 663-7331

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (sites)

1800 Dayton Avenue

Ames, IA 50010

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered by the Animal Welfare Regulations	B. Number of animals being bred, borned, or held for use in breeding, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		220	193	46	459
7. Hamsters	46	2850		950	3800
8. Rabbits			106		106
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goats		4			4
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

25-Nov-03

November 25, 2003

Annual report of the Center for Veterinary Biologics - Laboratory (CVB-L) for the period of October 1, 2002, through September 30, 2003.

1. All facilities are located at the 1800 Dayton Road location.
2. Statement of reasons for not using drugs in experiments involving pain and distress:

The CVB-L's main function is the testing of veterinary biologicals for safety, efficacy, and purity. Drugs to alleviate pain and distress produced by the infectious disease agents are contraindicated as they suppress the immune system causing the disease to be more severe and run a longer course. Most cases are also not allowed according to the requirements found in the 9 CFR, Chapter 113. Making sick animals comfortable and disturbing them as little as possible provides better treatment to these animals and quicker recovery than occurs by administering pain relievers. Euthanasia or curative treatments are employed as soon as allowed by the Animal Care and Use Committee approved animal use procedure.

3. Exceptions to adherence to the standards and regulations under the Act: None
4. Protocols involving unrelieved pain or distress were as follows:

See following attachments for Facility 42-F-008

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by a lay persons as well as scientists.

1. Registration Number: 42-F-0008
2. Number 104 (34 in Cat. E) _____ of animals in this study.
3. Species (common name) Guinea Pigs _____ of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Clostridium chauvoei and C. haemolyticum challenge tests- animals became ill from challenge with these organisms as required by 9 CFR 113.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Mandated by 9 CFR 113

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

APHIS, 9 CFR 113.106 and 113.107

Column E Explanation

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1. Registration Number: 42-F-0008
2. Number 99 (12 in Cat E) _____ of animals in this study.
3. Species (common name) Guinea Pigs _____ of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Potency testing of tetanus toxoids and antitoxins - animal getting insufficient protection from the tetanus antitoxin become sick from tetanus toxin challenge..

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Mandated by 9 CFR 113

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

APHIS, 9CFR 113.114 and 113.451

Column E Explanation

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1. Registration Number: 42-F-0008
2. Number 3800 (950 in Cat. E) _____ of animals in this study.
3. Species (common name) Hamsters _____ of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Evaluation of *Leptospira* Bacterins and maintenance of challenge cultures -

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Mandated by 9 CFR 113

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

APHIS, 9CFR 113.101, 113.102, 113.103, and 113.104 which are all
Leptospirosis tests.